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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/757,049	01/08/2001	Harold S. Bernstein	UCSF-020/02US	6383

25226 7590 11/06/2002

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EXAMINER

LAMBERTSON, DAVID A

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 11/06/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/757,049	<b>Applicant(s)</b> BERNSTEIN ET AL.	
	<b>Examiner</b> David A Lambertson	<b>Art Unit</b> 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-65 is/are pending in the application.
- 4a) Of the above claim(s) 1-55 and 62-65 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 56-61 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Election/Restrictions*

Applicant's election without traverse of Group VII in Paper No. 12 is acknowledged.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claims 1-55 and 62-65 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 12.

### *Priority*

Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 56-61 of this application. The claims are dependent on SEQ ID NOS: 13, 15, 21, 22 and 27, but these sequences are absent from the provisional application.

Applicant's claim for domestic priority under 35 U.S.C. 120 to US Application No 09/156,316 (henceforth the '316 application) is acknowledged. However, the application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 56-61

of this application. The claims are dependent on SEQ ID NOS: 13, 15, 21, 22 and 27, but these sequences are absent from the '316 application.

As each of the priority documents fails to provide adequate support for the claims as elected, priority is only granted for the filing date of the instant application, 8 January 2001.

### ***Specification***

The disclosure is objected to because of the following informalities: the Brief Description of the Drawings for Figure 2D fails to acknowledge the presence of the *S. pombe* Cdc5 sequence, both in the text of the drawing and by indication of the corresponding SEQ ID NO (it appears to be SEQ ID NO: 11). Applicant is required to amend the Brief Description of the Drawings to refer to the *S. pombe* Cdc5 gene, including the proper SEQ ID NO. A statement indicating this amendment does not introduce new matter is also required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 56-61 are rejected under 35 U.S.C. 102(a) as being anticipated by Lei *et al.* (*J. Cell Sci.* **113**: 4523-4531, 2000; IDS reference D66; see entire document).

Applicant is advised that the priority date has not been granted as claimed (see above for details), and that the inventive entity on the instant application is different from that listed on the article recited as prior art. Specifically, Shaun Coghlin is listed as an inventor, but is not listed as an author on the prior art document; also, Xiang-He Lei, Xun Shen and Xiao-Qin Xu are listed as authors on the prior art document but are not listed as inventors.

Concerning the claims, Lei *et al.* identifies each of the SEQ ID NOS as hCdc5 binding sites (e.g., Figure 1 shows SEQ ID NOS: 13, 14 and 20 in the consensus; Figure 2 shows SEQ ID NOS: 12 ( $\Delta 1$ ), 22 ( $\Delta 2$ ) and 27 ( $\Delta 3$ ); Figure 5A shows SEQ ID NOS: 15 (12(1) and 16 (12(2)) and describes using these sites in a vector to direct the transcription of the luciferase gene (a heterologous protein of interest) in cells that express hCdc5 (see for example page 4527, third complete paragraph). This procedure inherently measures the presence of hCdc5 in the cell, as per claim 60, as it follows from the teachings of the article that hCdc5 must be present in order for expression of the luciferase gene to occur.

Claim 56 is rejected under 35 U.S.C. 102(b) as being anticipated by Kuempel *et al.* (*New Biol.* **3**: 799-811, 1991; see entire document, especially Figure 6). Figure 6 shows a sequence corresponding to the reverse complement of SEQ ID NO: 13 of the instant application (see for example, the dif sequence of Figure 6).

Claim 56 is rejected under 35 U.S.C. 102(e) as being anticipated by Wagner *et al.* (US 6,355,415 B1; see entire document, especially for example SEQ ID NO: 5, residues 1899-1913).

Claim 56 is rejected under 35 U.S.C. 102(e) as being anticipated by Summers *et al.* (US 6,190,867 B1; see entire document, especially for example SEQ ID NO: 6, residues 41-52).

Claim 56 is rejected under 35 U.S.C. 102(a) as being anticipated by Hallsson *et al.* (*Genet.* **155**: 291-300, 2000; see for example page 292, right side, first complete paragraph).

Each of these references discloses isolated sequences comprising one or more of the sequences as claimed in the instant application. Although the prior art listed does not teach the binding of hCdc5 to these sequences explicitly, the fact that the sequences are identical to those of the instant application indicates that these sequences have the inherent property of binding hCdc5.

Because the Office does not have the facilities for examining and comparing the applicant's product with the products of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed products and the products of the prior art (e.g. that the products of the prior art do not possess the same material structural and functional characteristics of the claimed product). See *in re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

Applicant is claiming a sequence of 12 nucleotides, and the length and nature of this sequence is such that a large amount of prior art reads on the claim as recited. In the interest of limiting the size of the Office Action, not all prior art is disclosed in the art rejection (each sequence was found to have 100% homology with at least 45 other sequences as disclosed in either the patent or non-patent literature). The prior art as indicated is intended to represent a

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much larger embodiment of art as an indication to the applicant of the unpatentability of the sequences as claimed on their own. Including the limitations of claim 57, wherein the sequences are operably linked to a heterologous sequence in a vector, appears to be free of the art (with the exception of *Lei et al.*, recited above), and as per applicant's definition of "operably linked" on page 11, paragraph [0046]. Ammending the claims to recite the limitations of claim 57 in claim 56 would appear to be remedial at the time of this Office Action, provided applicant can traverse the rejection by *Lei et al.*

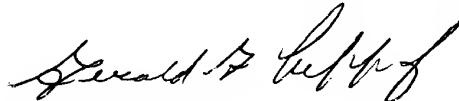
***Allowable Subject Matter***

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A Lambertson whose telephone number is (703) 308-8365. The examiner can normally be reached on 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



David A. Lambertson  
November 1, 2002

PATENT EXAMINER